

What is claimed:

1. An immunogenic composition for conferring protection in a host against disease caused by respiratory syncytial virus (RSV) comprising:

an F RSV antigen;

a G RSV antigen; and

at least one of M, M2, SH, NS1, NS2, N, or P RSV antigen.

2. The immunogenic composition of claim 1 wherein said composition is a mucosal vaccine.

3. An immunogenic composition for conferring protection in a host against disease caused by respiratory syncytial virus (RSV) comprising:

an M2 RSV antigen; and

at least one of F, G, M, SH, NS1, NS2, N, or P RSV antigen.

4. The immunogenic composition of claim 3 wherein said composition is a mucosal vaccine.

5. An immunogenic composition for conferring protection in a host against disease caused by respiratory syncytial virus (RSV) comprising:

an F RSV antigen;

a G RSV antigen;

an M2 RSV antigen; and

at least one of M, SH, NS1, NS2, N, or P RSV antigen.

6. The immunogenic composition of claim 5 wherein said composition is a mucosal vaccine.

7. A gene expression vaccine for conferring protection in a host against disease caused by respiratory syncytial virus (RSV) comprising:

a plasmid DNA cocktail comprising a combination of at least two RSV antigens selected from the group consisting of F, G, M, M2, SH, NS1, NS2, N, and P; wherein said plasmid DNA cocktail is coacervated with chitosan to form nanospheres.

8. The gene expression vaccine of claim 7 wherein administration does not alter airway hyperresponsiveness.

9. The gene expression vaccine of claim 7 wherein said vaccine is a mucosal vaccine.

10. The gene expression vaccine of claim 9 wherein said mucosal vaccine is conducive to oral administration.

11. The gene expression vaccine of claim 9 wherein said mucosal vaccine is conducive to intranasal administration.

12. The gene expression vaccine of claim 7 wherein administration of said vaccine induces IFN- $\gamma$  expression.

13. A method of immunizing a host against disease caused by infection with respiratory syncytial virus (RSV) comprising:

administering to said host an immunoeffective amount of a composition comprising:

a plasmid DNA cocktail comprising a combination of at least two RSV antigens selected from the group consisting of F, G, M, M2, SH, NS1, NS2, N, and P; wherein said plasmid DNA cocktail is coacervated with chitosan to form nanospheres.

14. The method of claim 13, wherein said administering is oral or intranasal.

15. The method of claim 13, wherein said administering does not induce airway hyperreactivity.

16. The method of claim 13, wherein said immunoeffective amount is administered in a single dose.

17. The method of claim 13, wherein said immunoeffective amount is about 1mg/kg host weight.

18. A method of making a gene expression vaccine comprising:

cloning cDNA for at least two respiratory syncytial virus antigens in a pVAX plasmid to form a plasmid DNA cocktail; and

coacervating the plasmid DNA cocktail with chitosan.

19. The method of claim 18 wherein said coacervating step results in the formation of nanospheres.

20. The method of claim 18 wherein the respiratory syncytial virus antigens are selected from the group consisting of F, G, M, M2, SH, NS1, NS2, N, and P.

# ABSTRACT

An effective prophylactic mucosal gene expression vaccine (GXV), made up of a cocktail of at least 4 different plasmid DNAs encoding corresponding RSV antigens, coacervated with chitosan to formulate nanospheres. In a murine model of RSV infection, intranasal administration with GXV results in significant induction of RSV-specific antibodies, nasal IgA antibodies, cytotoxic T lymphocytes, and IFN- $\gamma$  production in the lung and splenocytes. A single dose of GXV induces a drastic reduction of viral titers.

10 DC Doc #4123501

2025-05-15 10:07:30